

**Butler, Jennie C**

---

**From:** MGTATE@aol.com  
**Sent:** Monday, April 24, 2000 6:25 PM  
**To:** fdadockets@oc.fda.gov  
**Subject:** Docket number 97N-0436



FDA bottled water-  
final.doc

The attached document contains comments from the American Dental Association (ADA) concerning the Federal Register notice of February 22, 2000 on bottled water. A hard copy of the letter has been mailed to the FDA. In the event you can not open the file, the comments are provided below.

Michael Tate  
American Dental Association  
(202) 789-5175

April 24, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Comments on the Food and Drug Administration Notice of a Draft Study Report; Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water, 65 Fed. Reg. 8718-8722.

The American Dental Association (ADA or Association) submits the following comments concerning the above-identified notice. The ADA is a professional organization that represents approximately 144,000 licensed dentists (72 percent of the profession) in the United States. The ADA seeks to advance the art and science of dentistry and to promote high-quality dental care and the oral health of the American public.

The Food and Drug Administration's (FDA) draft report comments on the appropriateness and feasibility of six methods of informing customers of the contents of bottled water. The six methods listed are:

1. providing information on the label,
2. providing company contact information (address or phone number) on the label,
3. a combination of methods 1 and 2,
4. providing information in a pamphlet,
5. distributing information in pamphlets with bulk water deliveries, and
6. making information available on the Internet.

The FDA proposes to use methods #2, #3, and #5 to inform consumers about the contents of bottled water.

The ADA agrees with the FDA that the information should be provided by company contact through an address or phone number (#2) and by providing some content information on the label (#3). For bulk water deliveries, an information package should be provided with the bill or invoice (#5). The Association supports the quickest, most efficient and accurate means to disseminate information about bottled water, including the fluoride concentration, to consumers and dentists.

The Association believes that consumers need to know the fluoride concentration of the bottled water they consume, especially if bottled water is their primary source of drinking water. This information is also beneficial for health care professionals when making recommendations for patients regarding systemic and topical fluorides.

97N-0436

EMC 8

Published data shows that many bottled waters contain a sub-optimal level of fluoride. It is advisable for individuals, both adults and children, especially those who are at high risk for dental decay, to seek out and consume bottled water with an optimal (decay preventive) level of fluoride.

In addition, the ADA believes that consumers should know that the bottled water they consume does not exceed the maximum level of fluoride set by the FDA, thereby reducing the risk of mild dental fluorosis in young children. Due to the important role that fluoride plays in oral health, the Association believes the fluoride concentration of bottled water should also be readily available to health care professionals who may be involved in prescribing dietary fluoride supplements to enable them to better assess the total amount of fluoride consumed.

Thank you for the opportunity to comment on this notice..

Sincerely,

signed

Richard F. Mascola, D.D.S  
President

RFM:DJM:klp

April 24, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Comments on the Food and Drug Administration Notice of a Draft Study Report;  
*Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water*, 65 Fed. Reg. 8718-8722.

The American Dental Association (ADA or Association) submits the following comments concerning the above-identified notice. The ADA is a professional organization that represents approximately 144,000 licensed dentists (72 percent of the profession) in the United States. The ADA seeks to advance the art and science of dentistry and to promote high-quality dental care and the oral health of the American public.

The Food and Drug Administration's (FDA) draft report comments on the appropriateness and feasibility of six methods of informing customers of the contents of bottled water.

The six methods listed are:

1. providing information on the label,
2. providing company contact information (address or phone number) on the label,
3. a combination of methods 1 and 2,
4. providing information in a pamphlet,
5. distributing information in pamphlets with bulk water deliveries, and
6. making information available on the Internet.

The FDA proposes to use methods #2, #3, and #5 to inform consumers about the contents of bottled water.

The ADA agrees with the FDA that the information should be provided by company contact through an address or phone number (#2) and by providing some content information on the label (#3). For bulk water deliveries, an information package should be provided with the bill or invoice (#5). The Association supports the quickest, most efficient and accurate means to disseminate information about bottled water, *including the fluoride concentration*, to consumers and dentists.

The Association believes that consumers need to know the fluoride concentration of the bottled water they consume, especially if bottled water is their primary source of drinking water. This information is also beneficial for health care professionals when making recommendations for patients regarding systemic and topical fluorides.

Published data shows that many bottled waters contain a sub-optimal level of fluoride. It is advisable for individuals, both adults and children, especially those who are at high risk for dental decay, to seek out and consume bottled water with an optimal (decay preventive) level of fluoride.

In addition, the ADA believes that consumers should know that the bottled water they consume does not exceed the maximum level of fluoride set by the FDA, thereby reducing the risk of mild dental fluorosis in young children. Due to the important role that fluoride plays in oral health, the Association believes the fluoride concentration of bottled water should also be readily available to health care professionals who may be involved in prescribing dietary fluoride supplements to enable them to better assess the total amount of fluoride consumed.

Thank you for the opportunity to comment on this notice..

Sincerely,

*signed*

Richard F. Mascola, D.D.S  
President

RFM:DJM:klp